

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(3)(i) The Commission determines that the product meets the safety criteria in § 32.23; and

(ii) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 77 FR 43691, July 25, 2012]

#### § 32.23 Same: Safety criteria.

An applicant for a license under § 32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one

year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

(c) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(d)<sup>1</sup> In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in

<sup>1</sup>It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each 1 million exempt units distributed.

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Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

[34 FR 9027, June 6, 1969]

### § 32.24 Same: Table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk: active blood-forming organs; gonads: or lens of eye .....	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs .....	0.003	0.03	1.5	50

[34 FR 9329, June 13, 1969]

### § 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under

§ 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 9027, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 48 FR 12334, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

### § 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in